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KNOBLE, YOSHIDA & DUNLEAVY			EXAMINER	
EIGHT PENN CENTER			HAYMAN, IMANI N	
SUITE 1350, 1628 JOHN F KENNEDY BLVD			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,825	Applicant(s) MU, LIMIN
	Examiner IMANI HAYMAN	Art Unit 4116

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 5/12/06.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 May 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/02506) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In response to the Preliminary Amendment filed on May 12, 2006, claims 1-9 have been cancelled, and the newly added claims 10-21 are pending.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "4" in figures 1 and 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 10-13 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Cherif-Cheikh et al. (US Patent No. 6,902,543 B1).

Regarding claims 10 and 21, Cherif-Cheikh et al. discloses a syringe for powder medicament premixing comprising a sleeve (19); a plunger (25); a solvent bottle (11) that is positioned within said sleeve, said solvent bottle having a bottom opening that is provided with a first sealing plug that is made of a material selected from the group consisting of surgical rubber and innoxious rubber, a guiding recess being provided at a central portion of the first sealing plug; a solute bottle (13) having a bottom opening that is provided with a second sealing plug made of a material selected from the group consisting of surgical rubber or innoxious rubber and a guiding recess provided at a central portion of the second sealing plug, a piston being provided inside the solute bottle; a connecting tube (18) having two piercing ends; and a syringe needle (20) having two piercing ends (see figure 1).

Regarding claim 11, Cherif-Cheikh et al. discloses a syringe wherein said solvent bottle is provided inside an inner sleeve that is plugged into the solute bottle and both the solute bottle and the inner sleeve are positioned within the sleeve, the lower end face of the inner sleeve being formed with a hole that is defined in a piston (see column 7, lines 63-67 and column 8, lines 1-5).

Regarding claim 12, Cherif-Cheikh et al. discloses a syringe wherein a piston is provided on an upper end of the solvent bottle and under the plunger, and wherein one

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of the solvent bottle and the solute bottle is inserted into the other (see column 7, lines 63-67; column 8, lines 1-5; and column 9, lines 54-58).

Regarding claim 13, Cherif-Cheikh et al. discloses a syringe wherein a piston is provided on an upper end of the solvent bottle and under the plunger, and wherein the outer diameters of the solvent bottle and the solute bottle are identical and a pushing sleeve is provided on the upper edge of the piston inside the solute bottle (see column 9, lines 23-28; column 11, lines 64-67; and column 12, lines 1-5).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherif-Cheikh et al. (US Patent No. 6,902,543 B1) in view of Mohammad (US Patent No. 6,776,775 B1).

Regarding claim 14, Cherif-Cheikh et al. is silent on the restricting slot element. However, Mohammad discloses a syringe wherein the sleeve is provided with restricting slots, the restricting slots including a first restricting slot (10a) and a second restricting slot (10b), both of which are upside-down "L"-shaped and communicate with each other (see figure 3), and a plunger sleeve is integrated with the plunger (18), said plunger sleeve being provided with buckles (7) that are vertical to the plunger sleeve, the buckles being fitted into one of the first restricting slot or the second restricting slot, wherein two tongues (9b) are arranged on two sides of a lower edge of the plunger sleeve so as to be symmetrical to the axis thereof (see figure 10b), and two slots corresponding to the positions of the tongues are arranged on the two sides of the upper edge of the inner sleeve so as to be symmetrical to the axis thereof (see figures 14 and 15). Hence, at the time of invention, it would have been obvious to one skilled in the art to combine the teachings of Cherif-Cheikh et al. with Mohammad to incorporate a syringe capable of powder medicament premixing with restricting slots to act as a locking mechanism within the syringe body.

Regarding claim 15, Cherif-Cheikh et al. is silent on the arrangement of restricting slots. However, Mohammad discloses a syringe wherein said restricting slots (10a, 10b) are arranged at two sides of the sleeve and symmetrical to an axis of the sleeve (see figure 3). Hence, at the time of invention, it would have been obvious to

one skilled in the art to combine the teachings of Cherif-Cheikh et al. with Mohammad to incorporate a syringe capable of powder medicament premixing with oppositely arranged restricting slots to act as a locking mechanism within the syringe body.

Regarding claim 16, Cherif-Cheikh et al. is silent on the arrangement of the restricting slots. However, Mohammad discloses a syringe wherein said sleeve is provided with restricting slots (10a, 10b), which comprise two "L"-shaped sections communicated to each other (see figure 3), and further comprising a plunger sleeve that is integrated with the plunger (18) and is provided with buckles (7), which are inserted into the shorter portion on the upper end of the restricting slots (see figure 10b). Hence, at the time of invention, it would have been obvious to one skilled in the art to combine the teachings of Cherif-Cheikh et al. with Mohammad to incorporate a syringe capable of powder medicament premixing with restricting slots to act as a locking mechanism within the syringe body.

8. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherif-Cheikh et al. (US Patent No. 6,902,543 B1) in view of Mohammad (US Patent No. 6,776,775 B1) in further view of Peterson et al. (US Patent No. 5,520,639).

Regarding claims 17 and 18, Cherif-Cheikh et al. and Mohammed are silent on a viewing window. However, Peterson et al. discloses a syringe wherein a viewing port (744) is longitudinally arranged on the a cross-section of the sleeve (see figures 17 and 19). Hence, at the time of invention, it would have been obvious to one skilled in the art to combine the teachings of Cherif-Cheikh et al. and Mohammad with Peterson et al. to

incorporate a syringe capable of powder medicament premixing with a viewing port to observe the contents of the container.

Regarding claims 19 and 20, Cherif and Mohammad are silent on dual viewing ports. However, Peterson et al. discloses a syringe wherein said sleeve is provided with two viewing ports (744) that are arranged symmetrically to the axis of the sleeve in a longitudinal direction (see figures 17 and 19). Hence, at the time of invention, it would have been obvious to one skilled in the art to combine the teachings of Cherif-Cheikh et al. and Mohammad with Peterson et al. to incorporate a syringe capable of powder medicament premixing with a viewing port to observe the contents of the container.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to IMANI HAYMAN whose telephone number is (571)270-5528. The examiner can normally be reached on MONDAY THRU FRIDAY 7:30 AM TO 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOE CHENG can be reached on 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. H./
Examiner, Art Unit 4116
6/12/08

/Joe H Cheng/
Supervisory Patent Examiner
Art Unit 4116